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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,533	09/16/2003	Adam M. Gilbert	AM100279/WYNC-0677	3576

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EXAMINER	
HUANG, EVELYN MEI	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/663,533	GILBERT ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *26 and 33-52*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *see attachment*

Evelyn Huang
Primary Examiner
Art Unit: 1625

Attachment to Advisory Action

The 112 first paragraph for claims 26, 33-52 is maintained for reasons of record.

Applicants' arguments and the references submitted with the response have been fully considered but deem insufficient to obviate the rejection.

The 5HT1A receptor antagonist may abolish the body temperature decrease upon 5 HT1A activation (Ootsuka et al), may induce a decrease in REM sleep (Sorensen et al), or may decrease palatable food consumption in rats (Moreau et al). However, there is little support for the use of 5HT1A antagonist for treating all types of 'appetite control' (which encompass the opposing hyperphagia and anorexia), 'disorders of thermoregulation' (which includes the opposing hypothermia and hyperthermia), 'sleep dysfunction' (which covers both insomnia and narcolepsy) as recited in the instant claims. Since these are general classes of disorders embracing opposing and conflicting conditions arising from diverse origins, one of ordinary skill in the art recognizes that it is impossible to use a single $5HT_{1A}$ receptor antagonist compound of the instant to treat all these contradictory disorders.

In the instant $5HT_{1A}$ antagonist art, a high degree of unpredictability exists in that slight change in the structure of the compound would drastically alter its affinity and selectivity (Wijngaarden, Recl. Trav. Chim. Pays-Bas, 1993, 112:126-130, pages 129-130, Fig. 6, Fig. 7, Fig. 8), and the in vitro binding data do not necessarily reflect the in vivo activity, the required disclosure will be greater than for the disclosure of an invention involving a predictable factor such as a mechanical or electrical element. In re Vaeck, 20 USPQ 2d 1438. Since the above studies (and the studies described in Lanfumey et al. and Kwon et al) are based on 5HT1A antagonists structurally removed from the instant compound, one of ordinary skill in the art has little basis to extend the data in these references to the instant.

In conclusion, in view of the state of the art, the high degree of unpredictability of the art, the limited working examples, the scope of the claims does not commensurate with that of the objective enablement. Insufficient teaching and guidance have not been provided in the specification to enable one of ordinary skill in the art to make and use the invention as claimed without undue experimentation.